



Your Vision, Our Future

OLYMPUS SURGICAL TECHNOLOGIES EUROPE, Kuehnstraße 61, 22045 Hamburg, Germany

**To whom it may concern**

Your Reference:

Your Message from:

Our Reference:

Our Message from:

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Date: 21.10.2013

**Subject: Material of tubing in dosage pump of miniETD2 PAA and Maintenance kits of miniETD2 PAA / ETD3 PAA**

Dear customer,

In the framework of lifecycle management of ETD washer-disinfectors for flexible endoscopes, Miele and Olympus as well as their respective sub suppliers are constantly working on improvements of the existing portfolio.

In this context a sub supplier of Miele has changed a flexibilizer in the tubing inside the DOS3 pumps to a more eco-friendly one meeting the requirements of the Hazardous Substances Directive 2002/95/EC (RoHS). This tubing has been integrated in production of miniETD2 PAA and in the Maintenance kits for miniETD2 PAA and ETD3 PAA in August 2013.

Unfortunately, in the framework of additional extensive lifecycle testing, Miele has become aware of the fact, that the new flexibilizer influences the durability of the tubing in case of contact to the concentrate of EndoDis after a certain period of time. This could have an influence in the concentration of EndoDis in the cycle and the disinfection performance.

Based on the test results, miniETD2 PAA installed and miniETD2 PAA / ETD3 PAA maintained since August 2013 and equipped with this tubing material allow safe reprocessing. However, in order to avoid any potentially severe consequences and with

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Trade Registration Court: Amtsgericht Hamburg HRB 16 328

regard to our responsibility for the high safety in reprocessing, Miele and Olympus decided to exchange the tubing pro-actively.

The Olympus Service will contact you to arrange all necessary action.

Olympus and Miele regret any inconvenience which may occur by these measures.

In case of questions, please contact your local Olympus partner who will be delighted to be of help or make the necessary arrangements.

Please return the completed reply form to the denoted Olympus partner.

Kind regards,

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Dr. Andreas Brömmelhaus



Medical Device Safety Officer  
Regulatory Affairs  
Miele & Cie. KG

Daniel Wladow



Medical Device Safety Officer  
Regulatory Affairs  
Olympus Winter & Ibe GmbH

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